

**REMARKS**

In this Amendment, claims 20, 26-28, 30, and 32-33 are amended, and claim 31 is canceled. After entry of this Amendment, claims 20-30 and 32-33 will be pending in the application.

Applicants have amended claim 20 to remove the recitation of “(d) comparing said outlier proteins to known proteins to identify a unique outlier protein,” since this step is not essential to the invention.

Accordingly, claims 20, 26-28, 30, and 32-33 have been amended to remove the term “unique.”

No new matter has been added.

Applicants respectfully request entry of this Amendment.

Initially, Applicants wish to thank the Examiner and Primary Examiner Marschel for providing their time and helpful comments during the telephonic interview of September 7, 2004. A Statement of Substance of Interview is being concurrently filed herewith.

**I. Claim Rejections Under 35 U.S.C. § 101**

At page 2 of the Office Action, the Examiner rejects claims 20-28 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Specifically, the Examiner contends that the claims encompass methods performed on a computer that lack any physical act performed outside of the computer. Further, the Examiner contends that the claims appear to be directed to a method that merely manipulates numbers, abstract concepts or ideas, or signals representing any of the foregoing.

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At page 4 of the Office Action, the Examiner acknowledges Applicants' comments filed in response to the previous Office Action, and states that these arguments are unpersuasive.

First, regarding our comments that the claimed invention involves the manipulation of data representing proteins (physical objects), the Examiner contends that, while the sequences may represent physical objects, they are represented in an abstract means via data, and that the claims do not require that the methods actually use data representing physical objects.

Second, regarding our comments that the methods require protein sequence data that are pre-obtained, the Examiner contends that the claims do not recite such an obtainment step, and further, if the claims did broadly recite such a step, the claims may be reasonably interpreted to recite that these data are obtained from within a computer which is not a physical act.

Third, regarding our comments that the methods involve a step of validating the candidate anti-infective protein either computationally or physically, the Examiner contends that the claims do not recite that this validation step is necessarily a physical step.

Applicants' Response to the Section 101 Rejection

The Examiner has misapplied the law regarding statutory subject matter as interpreted by the Supreme court and the Federal Circuit.

The United States Supreme Court in *Diamond v. Diehr*, 450 U.S. 175, 187 (1981), in applying 35 U.S.C. § 101 to a process performed by a computer, held that "[a] claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer." The courts now recognize as commonplace that computer programs and mathematical algorithms and/or formulas are

patentable subject matter, so long as they are applied in a useful way. *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 47 USPQ2d 1596 (Fed. Cir. 1998) (finding that a data processing system for implementing an investment structure is patentable subject matter); *AT&T Corp. v. Excel Communications, Inc.*, 50 USPQ2d 1447 (Fed. Cir. 1999) (finding that a telecommunications computer program was patentable subject matter even though the program embodied simple mathematical principles); *See also, In re Alappat*, 31 USPQ2d 1545 (Fed. Cir. 1994).

**In fact, the claims need not even recite a physical act or limitation to satisfy section 101, that is, the entire process may be performed by a computer. In refuting the requirement for a physical limitation the Federal Circuit stated that “physical limitations analysis seems of little value because ‘after *Diehr* and *Alappat*, the mere fact that a claimed invention involves inputting numbers, calculating numbers, outputting numbers, and storing numbers, in and of itself, would not render it nonstatutory subject matter’ ....” *AT&T Corp*, 50 USPQ2d 1447 at 1453.**

The facts in the case of *Arrhythmia Research Technology, Inc. v. Corazonix, Corp.*, 22 USPQ2d 1033 (Fed. Cir. 1992) are analogous to those of the present case. In *Arrhythmia Research Technology*, the patentee obtained a patent directed to a method of analyzing electrocardiac signals, the entire method being performed by a computer. *Id at 1034*. Claim 1 of the patent at issue recited:

1. A method for analyzing electrocardiograph signals to determine the presence or absence of a predetermined level of high frequency energy in the late

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QRS signal, comprising the steps of: converting a series of QRS signals to time segments, each segment having a digital value equivalent to the analog value of said signals at said time; applying a portion of said time segments in reverse time order to high pass filter means; determining an arithmetic value of the amplitude of the output of said filter; and comparing said value with said predetermined level. *Id* at 1035.

In finding that claim 1 was directed toward statutory subject matter, the Federal Circuit found that the input signals “are not abstractions; they are related to the patient’s heart function,” and further, that claim 1 does not seek to patent a mathematical formula in the abstraction, but merely to patent its use in connection with the claimed process of analyzing electrocardiac signals. *Id* at 1038.

In the present case, the Examiner states at page 4 of the Office Action that the claims are directed to a method that merely manipulates numbers, abstract concepts or ideas, or signals representing any of the foregoing. Applicants submit that, as held in *State Street Bank & Trust Co.*, a claimed invention is statutory subject matter even though it manipulates numbers, so long as it is directed to a useful purpose, for example, identifying candidate anti-infectives. Applicants further submit that, as in *Arrhythmia Research Technology* where the signals represented a patient’s heart function, the presently claimed invention does not merely manipulate abstract concepts, ideas, or signals representing such. The signals in the instant case represent proteins of a pathogenic organism. Therefore, the claimed method does not merely manipulate numbers, abstract concepts or ideas, or signals representing any of the foregoing,

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because it is drawn to the useful purpose of identifying candidate anti-infectives and the signals represent proteins of a pathogenic organism.

Also in the present case, at page 4 of the Office Action the Examiner asserts that a claim is drawn to nonstatutory subject matter if it “consists solely of mathematical operations without some claimed practical application.” Indeed, this statement of the law supports the position that the present invention is statutory subject matter. The present invention employs computational methods to identify candidate anti-infectives from among proteins of a pathogenic organism. Such is clearly a practical application, and thus the claimed method does not consist solely of mathematical operations without some claimed practical application as the Examiner contends. See, e.g. *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 47 USPQ2d 1596 (Fed. Cir. 1998) (finding that a data processing system for implementing an investment structure is patentable subject matter); *AT&T Corp. v. Excel Communications, Inc.*, 50 USPQ2d 1447 (Fed. Cir. 1999) (finding that a telecommunications computer program was patentable subject matter); *Arrhythmia Research Technology, Inc. v. Corazonix, Corp.*, 22 USPQ2d 1033 (Fed. Cir. 1992) (finding that a computerized method of analyzing a patients EKG was patentable subject matter).

**Finally, and as briefly discussed during the telephonic interview with the Examiner on September 7, 2004, the MPEP § 2106 (page 2100-15 of Latest Revision May 2004) provides an example of a process claim that is directed to statutory subject matter (see second column). This exemplary claim does not recite a physical transformation step. Specifically, the first step of the claim recites converting signals to time segments, that is, the electrical signals have already been generated prior to performing the first step of the**

**claimed process. Further, the MPEP states that in this example, “the transformation occurs when heart activity is measured and an electrical signal is produced.” See the attached photocopy of page 2100-15 of the MPEP.**

Thus, the Examiner has misapplied the law regarding statutory subject matter under 35 USC § 101 as interpreted by the United States Supreme Court and the Court of Appeals for the Federal Circuit, because the claims need not recite a physical transformation step to be statutory subject matter. Accordingly, Applicants respectfully request that this rejection be withdrawn.

## **II. Claim Rejections Under 35 USC § 112, First Paragraph--Written Description**

At page 5 of the Office Action, the Examiner rejects claim 33 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner contends that the support provided for new claim 33 in the Amendment filed February 2, 2004 (page 7, line 4 of the specification) does not provide sufficient support for the phrase "unique outlier protein can elicit an immune response."

### **Applicants' Response to the Written Description Rejection**

In determining whether an amendment is supported by the specification as filed, MPEP § 2163.02 summarizes the relevant inquiry as follows: does the description clearly allow persons of ordinary skill in the art to recognize that Applicants invented what is claimed?

Applicants submit that page 7 of the specification states that “these outlier proteins are either virulence proteins or *antigens* or used as drug targets.” Indeed, antigens are proteins that elicit at least an antibody response. Therefore, the disclosure allows persons of ordinary skill in

the art to recognize that Applicants invented the method where the outlier protein elicits an immune response.

In addition, the specification repeatedly states that outlier proteins are “vaccine candidates.” As vaccines must necessarily elicit an immune response, it seems clear from the specification that Applicants intend some outlier proteins to elicit an immune response and thereby be vaccine candidates (successful candidates eliciting a protective immune response).

Thus, Applicants believe that the Examiner has misapplied the written description requirement, and Applicants respectfully request withdrawal of this rejection.

### **III. Claim Rejections Under § 112, First Paragraph-- Enablement**

At page 6 of the Office Action, the Examiner rejects claim 31 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Claim 31 is canceled rendering the rejection moot. Applicants respectfully request withdrawal of this rejection.

### **IV. Claim Rejections Under 35 USC § 112, Second Paragraph**

Claims 20-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Specifically, the Examiner contends that the term “unique outlier protein” is unclear because the specification does not sufficiently define the parameters that make an outlier protein “unique.”

Applicants have removed from the claims the requirement that the outlier protein be “unique,” as it is not essential to the invention. Outlier proteins are useful as anti-infectives whether they are unique or not.

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Accordingly, Applicants believe that claims 20-33 are not indefinite, and Applicants respectfully request that this rejection be withdrawn.

**V. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

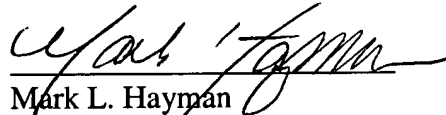
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**23373**

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determine when the time period has been reached in the curing process and then opening the mold at that stage.

- A method of controlling a mechanical robot which relies upon storing data in a computer that represents various types of mechanical movements of the robot, using a computer processor to calculate positioning of the robot in relation to given tasks to be performed by the robot, and controlling the robot's movement and position based on the calculated position.

Examples of claimed processes that do not achieve a practical application include:

- step of "updating alarm limits" found to constitute changing the number value of a variable to represent the result of the calculation (*Parker v. Flook*, 437 U.S. 584, 585, 198 USPQ 193, 195 (1978));
- final step of "equating" the process outputs to the values of the last set of process inputs found to constitute storing the result of calculations (*In re Gelnovatch*, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979); and
- step of "transmitting electrical signals representing" the result of calculations (*In re De Castelet*, 562 F.2d 1236, 1244, 195 USPQ 439, 446 (CCPA 1977) ("That the computer is instructed to transmit electrical signals, representing the results of its calculations, does not constitute the type of 'post solution activity' found in *Flook*, [437 U.S. 584, 198 USPQ 193 (1978)], and does not transform the claim into one for a process merely using an algorithm. The final transmitting step constitutes nothing more than reading out the result of the calculations.")); and
- step of displaying a calculation as a gray code scale (*In re Abele*, 684 F.2d 902, 908, 214 USPQ 682, 687 (CCPA 1982)).

#### **- Manipulation of Data Representing Physical Objects or Activities (Pre-Computer Process Activity)**

Another statutory process is one that requires the measurements of physical objects or activities to be transformed outside of the computer into computer data (*In re Gelnovatch*, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979) (data-gathering

step did not measure physical phenomenon); *Arrhythmia*, 958 F.2d at 1056, 22 USPQ2d at 1036), where the data comprises signals corresponding to physical objects or activities external to the computer system, and where the process causes a physical transformation of the signals which are intangible representations of the physical objects or activities. *Schrader*, 22 F.3d at 294, 30 USPQ2d at 1459 citing with approval *Arrhythmia*, 958 F.2d at 1058-59, 22 USPQ2d at 1037-38; *Abele*, 684 F.2d at 909, 214 USPQ at 688; *In re Taner*, 681 F.2d 787, 790, 214 USPQ 678, 681 (CCPA 1982).

Examples of this type of claimed statutory process include the following:

- A method of using a computer processor to analyze electrical signals and data representative of human cardiac activity by converting the signals to time segments, applying the time segments in reverse order to a high pass filter means, using the computer processor to determine the amplitude of the high pass filter's output, and using the computer processor to compare the value to a predetermined value. In this example the data is an intangible representation of physical activity, i.e., human cardiac activity. The transformation occurs when heart activity is measured and an electrical signal is produced. This process has real world value in predicting vulnerability to ventricular tachycardia immediately after a heart attack.
- A method of using a computer processor to receive data representing Computerized Axial Tomography ("CAT") scan images of a patient, performing a calculation to determine the difference between a local value at a data point and an average value of the data in a region surrounding the point, and displaying the difference as a gray scale for each point in the image, and displaying the resulting image. In this example the data is an intangible representation of a physical object, i.e., portions of the anatomy of a patient. The transformation occurs when the condition of the human body is measured with X-rays and the X-rays are converted into electrical digital signals that represent the condition of the human body. The real world value of the invention lies in creating a new CAT scan image of body tissue without the presence of bones.